Document Structure

Introduction: General Laboratory Information

Name of Laboratory: Scientific Crime Detection Laboratory

State of Alaska (SOA), Department of Public Safety (DPS)

Approximate population size served: 700,000 (2010 census)

The laboratory does not currently use a contract laboratory.

The laboratory performs technical review of data from casework submitted by SOA Law Enforcement agencies to contract/vendor laboratories for potential entry and search in CODIS.

The laboratory participates in NDIS

Technologies used: STR (Short Tandem Repeats)

Number of staff:

DNA analysts: seven

DNA casework trainees: 3

DNA Technicians: 1

Laboratory support personnel: 1 (paralegal)

DNA Technical Manager: On-site – 1

CODIS Administrator (Casework + Database): On-site – 1

Last audit conducted on:

Internal Annual – 12-14, September 2011

External Annual – 4-8, October 2010

Audit document discussion used:

2011 Internal annual audit: Revision effective 1 September 2011

2010 External annual audit: Revision effective 1 July 2009

Expert Systems available for use: None

The database laboratory does not routinely process casework known reference samples.

Goals and Objectives:

Reference: The laboratory Quality Assurance manual for quality standards which are applicable to all disciplines of the crime laboratory

Chapter 1: Scope

References:

1. FBI Quality Assurance Standards (QAS) documents: Version(s) effective 01 September 2011 for Forensic DNA Testing laboratories and DNA Databasing laboratories.

The DNA QA manual is based on the latest version(s) of the FBI QAS document(s) and the reader is advised to refer to these FBI QAS documents for detailed discussions and interpretations of the relevant quality standards and their sub-categories.

2. The laboratory Safety Manual for documentation of an environmental health and safety program.

3. The Forensic Biology Procedures and Work Instructions manuals for information pertaining to analytical procedures and/or work instructions for the specific reagents and instruments for DNA analysis and data interpretation.

4. The DNA Training Manual

Chapter 2: Definitions

An **error** is defined as an action or event that leads to an inaccurate conclusion in a DNA report (casework or proficiency test) released by the laboratory. Errors will be addressed and documented in corrective action reports (CARs).

In addition, please refer to:

Standard 2 – FBI Quality Assurance Standards (QAS) documents for Forensic DNA Testing laboratories and DNA Databasing laboratories – version(s) effective 01 September 2011.

Chapter 3: Quality Assurance Program

The laboratory has established and maintains a documented quality system that is appropriate to the testing activities conducted by the laboratory. The quality system is at least equivalent to and/or more stringent than what is required by FBI Quality Assurance Standards (QAS) (versions effective 01 September 2011) document for Forensic DNA testing laboratories and DNA databasing laboratories.

The quality system of the laboratory is documented in manuals that include and reference the following elements as listed in the contents page of this manual:

Goals and objectives,

Organization and management,

Personnel,

Facilities,

Evidence/Sample control,

Validation,

Analytical procedures,

Equipment calibration and maintenance,

Documentation/reports,

Review,

Proficiency testing,

Corrective action,

Audits,

Safety,

and,

Outsourcing.

Document Retention policies:

Please refer to the laboratory Quality Assurance manual regarding procedures pertaining to document retention policies for the following:

Proficiency tests,

Analytical results,

Sample receipt and processing records,

Sample retention,

Corrective actions,

Audits,

Training records,

Continuing education,

Case files,

and,

Court testimony monitoring.

The policies pertaining to hit confirmation are documented in the laboratory CODIS manual.

The quality system as applicable to DNA is reviewed annually (calendar year) independent of the audit required by FBI QA Standard 15 (Please see Chapter 15).

The manual(s) review is performed under the direction and documented approval of the DNA technical manager.

Checklists are maintained as hard copies for each of the manuals listed below until all required signatures/initials of the analysts along with the date their annual review of relevant documents was completed. The checklists are then converted to an electronic format (pdf file) and stored in LIMS.

This annual review document list currently includes the DNA Quality Assurance manual, Forensic Biology manuals (procedures and work instructions), DNA Training Manual, Biological Screening Training Manual, and, CODIS Manual.

Chapter 4: Organization and Management

The laboratory has a managerial staff with the authority and resources needed to discharge its duties and meet the requirements of the FBI Quality Assurance Standards (QAS) documents (versions effective 01 September 2011) for forensic DNA testing laboratories and DNA databasing laboratories,

The laboratory has an on-site technical manager who is accountable for the technical operations and an on-site CODIS administrator (database and casework) who is accountable for CODIS operations at the laboratory.

In accordance with Appendix B of the FBI Quality Assurance Standards document, a DNA analyst who meets the educational qualifications and work experience to fulfill the duties of DNA technical manager has been identified in the event that position is vacated by the current technical manager.

The laboratory meets the requirements of having at least two full time employees who are qualified DNA analysts.

The laboratory organizational chart contains documentation that specifies the responsibility, authority, and interrelation of all personnel who manage perform and/or verify work affecting the validity of DNA analysis.

The Forensic Biology DNA Quality Assurance manual supplements information contained in the laboratory Quality Assurance Manual.

Chapter 5: Personnel

Laboratory personnel have the education, training and experience commensurate with the examination and testimony provided.

The laboratory quality manual maintains written job descriptions for all personnel to include responsibilities, duties and skills.

The laboratory has a documented training program for qualifying all analysts.

The training program uses a DNA training manual and related training checklist that specify applicable DNA analytical procedures that the analyst(s) will perform.

The training program employs practical exercises that include the DNA methodologies used in database sample analysis and examination of a range of samples routinely encountered in casework.

Database analysts, may be authorized, when required, to assist casework analysts by performing analytical tasks as directed and monitored by the casework analyst(s). A memorandum addressing this authorization will be kept on file with the laboratory Quality Assurance Manager.

The databasing laboratory does not routinely process known or casework reference samples unless this task is part of duties assigned and carried out as stated in this memorandum.

The laboratory's training program documented in the training manual is designed to teach and assess the technical and scientific skills and knowledge required to perform DNA analysis and it includes documentation of the successful completion of competency test(s).

In the event an analyst possessing prior forensic experience in DNA analysis is hired, the technical manager will assess and document the adequacy and relevance of the previous training of this analyst. This analyst will complete a modified training program that will be evaluated and documented by the technical manager.

Prior to participating in independent database analysis and/or DNA casework, all analysts regardless of prior experience will successfully complete competency test(s) covering routine DNA methodologies to be used.

In case of an extended absence (equal to or greater than 3 months) from the laboratory, an analyst may be required to successfully complete at least an internal competency test prior to resuming sample processing / DNA analysis duties

The laboratory has a documented program to ensure that technical qualifications are maintained through continuing education.

The technical manager, CODIS administrator (database and casework) and each DNA analyst will maintain documentation of attendance at seminars, courses, professional meetings and/or training sessions that consist of subject areas relevant to developments in genetics and DNA analysis and typing.

The cumulative duration of each annual (calendar year) training session(s) will be at least eight hours. This information will also be documented in the analyst's SOQ (statement of qualifications).as well as in LIMS.

If continuing education is conducted internally by the laboratory, the retained documentation will include the title of the program, a record of the presentation (electronic and/or hard copy), date(s) of the training, attendance list and curriculum vitae of the presenter(s).

If continuing education is conducted externally, the laboratory will retain documentation that includes one or more of the following: Certificate of attendance, program agenda/syllabus and travel related documentation. Such documentation will be maintained in the laboratory's LIMS (laboratory information management system).

For continuing education that is based on multimedia or internet delivery, the training:

(i) Will be subject to review of and approval by the DNA technical manager,

(ii) Duration of the program or time required to complete the program formally recorded in the laboratory's retained document, and,

(iii) Proof of completion submitted to the technical manager for review and approval.

The laboratory has a program approved by the technical manager for the annual review of scientific literature that documents (hard copy of publication/research article and circulation checklist) the ongoing reading of scientific literature. The laboratory maintains physical and electronic access, as required and applicable, to a collection of scientific literature relevant to DNA analysis.

The DNA technical manager will satisfy/satisfies the requirements for degree/education, experience and duties as follows: The technical manager has a graduate degree in Human Genetics with semester hours that exceed the minimum requirements stated under FBI QA Standard 5 in the subject areas of biochemistry, genetics, molecular biology and statistics or population genetics.

The technical manager educational requirements as well as the experience requirements will comply with Standard 5 of the FBI Quality Assurance Standards (QAS) document for forensic DNA testing laboratories and DNA databasing laboratories (versions 01 September 2011).

The DNA technical manager has successfully completed the FBI sponsored auditor training as well as the ASCLD/LAB-International sponsored ISO Assessor Training.

The DNA technical manager oversees the technical operations of the DNA laboratory.

The technical manager has the authority to initiate, suspend and resume DNA database and casework analytical operations for the laboratory or an individual.

The technical manager will evaluate and document approval of all validations and methods used by the laboratory and propose new or modified analytical procedures to be used by analysts.

The technical manager will review and document the review of academic transcripts and training records for newly qualified analysts and approve their qualifications prior to their conducting independent database or casework analysis.

The technical manager will approve the technical specifications for outsourcing agreements.

The technical manager will evaluate and document the review of internal and external DNA audit documents and, if and when applicable, approve corrective action(s).

The technical manager will review, at a minimum, annually (calendar year) the laboratory procedures and will document completion of such review.

The technical manager will review and approve the training, quality assurance, and proficiency testing programs in the DNA laboratory.

The technical manager is a full time employee of the laboratory and is available and accessible to the laboratory to provide on-site/ telephonic/ electronic consultation as needed.

DNA technical manager contingency plan: Please refer to Chapter 4

The CODIS administrator (database and casework) is a full time employee of the laboratory and satisfies the requirements for degree/education, experience and duties. Please refer to the CODIS manual for detailed information regarding the CODIS administrator.

Each DNA analyst who is an employee of the laboratory will meet and/or exceed the degree and educational requirements stated in Standard 5 of the FBI Quality Assurance Standards (QAS) document for forensic DNA testing laboratories and DNA databasing laboratories (version 01 September 2011).

Each DNA analyst will have at a minimum, a BA/BS degree in relevant subject areas.

College coursework for analysts covers the subject areas of biochemistry, genetics, molecular biology and statistics and/or population genetics.

In the event completed coursework have titles or descriptors other than those listed in Standard 5, the technical manager will review the documentation provided through supporting materials such as transcripts / syllabus / course details and documented this evaluation towards the approval of compliance with this Quality Assurance Standard. A memorandum issued by the DNA technical manager, is maintained by each analyst as part of the training materials to document approval of educational requirements.

Each new analyst will have a minimum of six months of human forensic DNA testing training in a forensic casework/database laboratory prior to beginning independent work.

Each new analyst will complete training in the analysis of the range of samples routinely encountered in database analysis and/or forensic casework.

Each analyst will successfully complete a competency test before beginning independent DNA analysis.

Competency tests following extended absences will be, at a minimum, internally evaluated as stated earlier in this chapter.

Chapter 6: Facilities

The laboratory is designed (please refer to laboratory quality assurance manual) to ensure the integrity of the analyses and samples / evidence.

Access to the laboratory is controlled and limited in a manner that prevents access by unauthorized personnel. All exterior entrance/exit points have security control and the distribution of security devices such as keys and cards is documented and limited to personnel designated by laboratory management.

Technical procedures such as sample screening and DNA extraction that precede DNA amplification by PCR (Polymerase Chain Reaction) are conducted in separate spaces/areas.

Amplified DNA products (including those generated by Real Time PCR quantification) are generated, processed and maintained in laboratory area /room separate from evidence examination, DNA extractions and PCR set-up areas.

The doors between rooms containing amplified DNA and other areas are closed at all times except for passage.

The laboratory maintains schedules and follows written procedures for cleaning and decontaminating facilities and equipment.

Example: DNA extraction worksheet; routine cleaning lists are maintained and archived, cleaning duties are performed, documented and archived by the DNA technician.

Chapter 7: Sample / Evidence Control

The laboratory has and follows a documented sample inventory and evidence control system to ensure the integrity of database samples and physical evidence.

All database samples and evidence items are marked with unique identifiers on the packaging.

The laboratory has established criteria for defining the difference between evidence and work product.

The laboratory has and follows documented policies for the disposition of evidence and/or extracts and sample consumption.

Work product, is material that that is generated as a function of analysis, which may include extracts, spermatozoa search slides/extract slides, amplified products and amplification tubes or plates.

DNA analysis related work product such as PCR amplified products are discarded once the data reviews have been completed and the material is no longer needed for further analysis.

Work product such as DNA extracts will be routinely discarded after data review is completed and the case report issued. This implies that sufficient quantity of the original item remains for retesting, if required.

If the entire original item (e.g., penile swabs, fingernail scrapings, hand swabs, miscellaneous contact DNA items) is used for DNA extraction owing to limited amounts of biological material, then, at least fifty percent of the DNA extracted from that item will be tagged as evidence and retained by the laboratory for retesting, if and when required.

In situations where the entire item of evidence has been used up/consumed in the process of DNA extractions and, quantitation results suggest that the entire volume of DNA extract will be required for PCR amplification in order to attempt to obtain interpretable data, the laboratory shall contact the Department of Law to request permission to use/consume the entire extract.

Casework analysis of such limited sample(s) extract(s) will not proceed until documented approval by the appropriate agency is received by the laboratory. (Please see exception in unknown suspect cases on following page).

In general, the laboratory retains or returns a portion of the evidence or extract where and when possible.

Work product such as the amplified products generated as a result of Real Time Quantitation procedures will be routinely discarded irrespective of the amount of the original item of evidence.

Note: In unknown suspect cases, the entire sample may be used up/consumed in analysis without prior Department of Law notification and/or approval.

The laboratory employs various methods to distinguish each sample throughout the processing from extraction through data analysis by the use of a batch related unique identifier.

Information regarding samples such as internal control samples and allelic ladders analyzed in a batch is located in the central log pertaining to that batch of samples.

Specific case related information is located in case folders that may be hard copy and/or electronic versions of the information.

The databasing laboratory does not routinely process known/reference samples from forensic cases.

Forensic questioned and casework related reference samples are analyzed by the DNA casework analysts.

The databasing laboratory and/or the evidence section of the laboratory maintain documentation pertaining to the identity, collection, receipt, storage and disposition of database samples.

The laboratory retains the database sample for retesting for quality assurance and sample confirmation purposes whenever possible.

Database samples are considered as reference material and are not as evidence.

For casework samples, an electronic chain of custody record is maintained.

The chain of custody includes the signature and/or initials of each individual receiving or transferring evidence, with the corresponding date for each transfer as well as a corresponding identifier that specifies each evidentiary item transferred.

The chain of custody record provides a comprehensive, documented history for each item of evidence over which the laboratory has control from the time that item is transferred to the laboratory's custody.

Chain of custody records are sufficiently secure and detailed and are accessible for review.

The laboratory has and follows procedures (please refer to the laboratory Quality Assurance manual and Forensic Biology procedures and work instructions manuals) designed to minimize loss, contamination and/or deleterious change of evidence and work product in progress.

The laboratory has secure, controlled-access areas for evidence storage and work product in progress including environment control consistent with the form or nature of the sample.

Chapter 8: Validation

The laboratory uses validated methods for DNA analysis.

Whenever developmental validation has been completed by the vendor and/or another institution, our laboratory will perform internal validation as appropriate prior to implementing a process or a product for database samples and forensic DNA analysis.

If developmental validation is indicated for a product or process, the following studies will be performed as applicable, appropriate and relevant. The documented results will form the basis of the analytical procedures and work instructions:

Genetic marker characterization,

Species specificity,

Sensitivity studies,

Stability studies,

Reproducibility,

Case work - type samples,

Database - type samples,

Population studies,

DNA Mixture studies,

Precision studies

and,

Accuracy studies.

PCR based studies will include at a minimum:

Reaction conditions,

Assessment of differential and preferential amplification,

Effects of multiplexing,

Assessment of appropriate controls,

and,

Product detection studies (as appropriate and applicable).

Peer reviewed publications of the underlying scientific principles will be relied on and evaluated and documented for performing the appropriate developmental validations.

The results of the validations study/studies will be documented and retained in hard copy and/or electronic format.

Internal validation studies of manual and robotic procedures will be evaluated, conducted, reviewed, and approved by the DNA technical manager prior to implementation.

The results of the internal validation studies will be documented, summarized (if appropriate) and retained/archived.

Internal validation studies will include, as applicable, the following:

Database–type samples,

Case work-type samples (known / non-probative evidence /mock evidence samples / old proficiency test samples),

Reproducibility,

Precision,

Sensitivity and stochastic studies,

DNA mixture studies,

and,

Contamination assessment.

The laboratory maintains quality assurance parameters and interpretation guidelines (including mixture interpretation guidelines) that have been defined pursuant to internal validation studies.

(Please refer to the laboratory Quality Assurance manual and Forensic Biology procedures and work instructions)

A change in the detection platform and/or test kit(s) will require an internal validation before the changes are implemented.

The analysts will successfully complete a competency test using the DNA analysis protocols prior to implementation/incorporation into database and/or casework applications.

The modified protocols will be evaluated by comparison to the original protocols using comparable/similar DNA samples prior to implementation in database and/or casework applications.

The laboratory will evaluate each additional and/or modified critical instrument by conducting a performance check prior to its use in database or casework analysis (Chapter 10).

The laboratory will evaluate software upgrades by conducting a performance check(s) prior to use in database and/or casework analysis.

Chapter 9: Analytical Procedures

The laboratory has and follows written analytical protocols (Forensic Biology procedures and work instructions) approved by the DNA technical manager.

The technical manager reviews (Chapter 3) and updates (when applicable) the analytical protocols as needed and, at least once annually (each calendar year).

The annual review (and any interim period updates, if applicable) helps to document updates to be incorporated into the manual(s) during the next scheduled manual update. The laboratory does not permit interim updates to the manuals by hand or by electronic means.

The laboratory has a documented protocol (Forensic Biology procedures/work instructions) for each analytical method used.

The analytical protocols (procedures / work instructions) specify reagents, sample preparation, extraction methods, equipment, and controls that are standard for DNA analysis and data interpretation.

The Forensic Biology procedures/work instructions manuals include protocols for differential extraction of biological stains that contain sperm.

The laboratory uses reagents that are suitable for the methods employed.

The laboratory has written protocols for documenting commercial reagents and for formulation of in-house reagents, if applicable.

The commercial reagents are labeled in a manner which clearly identifies the reagent as well as the expiration date provided by the manufacturer.

If no manufacturer specified expiration date is available, the laboratory will determine and assign an appropriate expiration date for the reagent.

Reagents or chemicals purchased in dry powder form may be used up to a period of 15 years (expiration date to coincide with 15 years from date of receipt of the item).

Reagents or chemicals purchased as solutions or fluids may be used up to period of 10 years (expiration date to coincide with 10 years from date of receipt of item).

In-house reagents, if prepared, will be labeled with the identity of the item, the date of preparation, expiration date and the identity of the individual preparing the reagent.

All such information is duly documented and available for review.

Non-critical reagents such as Permount or Xylene may be used beyond the manufacturer's recommended expiration dates if the quality of this reagent is assessed and deemed appropriate for the scope of intended use – i.e., use on microscopy slides. Such items can be used until they no longer adequately satisfy the intended use- for example, the Permount becomes too viscous or the Xylene fails to reduce the viscosity of the Permount or renders the Permount too opaque to view the materials on the slide.

The laboratory has identified reagents to be deemed critical reagents (Forensic Biology procedures and/or work instructions manual(s) for information and rationale for designating reagents as critical or non-critical).

Critical reagents require evaluation/verification before use in database sample and casework analyses.

Critical reagents will include, at a minimum, the following:

(i) Test kits or systems for performing quantitative PCR
(ii) Test kits or systems for performing genetic typing
(iii) Thermostable DNA polymerase if it has not been evaluated as an integral part of the test kit components
(iv) Primer sets if they have not been evaluated as an integral part of the test kit components
(v) Allelic ladders used for genetic analysis if they have not been evaluated as an integral part of the test kit components.

The laboratory has and follows a documented procedure for the resolution, verification, and reporting/notification of database matches (CODIS manual).

The laboratory quantifies the amount of human DNA in forensic samples prior to nuclear DNA amplification.

DNA quantification is not mandatory for single source known/reference samples, database samples and reagent blanks as long as the reagent blanks will be amplified at the most stringent/sensitive set of conditions as a forensic sample in that batch/set of samples..

The laboratory monitors analytical protocols using appropriate controls and standards.

Controls and reference standards are used during quantification procedures.

Positive and negative amplification controls are associated with the samples being typed.

Positive and negative controls associated with the database and forensic samples being typed are processed / amplified concurrently with the samples at all loci using the same primers as the database and forensic samples.

Reagent blank controls associated with each extraction set being analyzed are extracted concurrently with the database and forensic samples.

The reagent blanks are amplified using the same primers as the database and forensic samples on the same instrument model as the database and forensic samples and at the same concentration conditions as required by the forensic samples containing the least amount of DNA.

The reagent blanks are typed using the same instrument model as the database and forensic samples, at the most stringent/sensitive conditions as the forensic samples and the most sensitive volume conditions of the forensic extraction set.

The laboratory checks its DNA protocols annually (and whenever substantial/substantive changes are made to a procedure or work instruction) against an appropriate and available NIST standard reference material (SRM).

The laboratory has and follows established and documented guidelines (DNA procedures and/or work instructions manuals) for the interpretation of short tandem repeat (STR) data.

The laboratory verifies that all control results meet the laboratory's interpretation guidelines for all reported results and for data to be entered into CODIS.

The 1996 National Research Council report / recommendation is used as a guideline for the statistical interpretation of a DNA profile for a given population and for assessment of relatedness among the individuals in that population. These calculations are derived from established and published population database research studies appropriate for the calculation and the population of the State of Alaska.

The laboratory has and follows specific documented statistical interpretation guidelines relevant to population structure, distribution and size relevant to the State of Alaska.

The laboratory has and follows documented protocols (DNA procedures/work instructions) for:

Mixture interpretation to include major and minor contributors,

Inclusions (failure to exclude an individual as a source of DNA in a sample)

Exclusions,

and,

Guidelines, recommendations, policies for reporting results, conclusions and statistics.

The laboratory has and follows a documented policy and procedures (please refer to the laboratory Quality Assurance manual) for detecting and controlling contamination.

Contaminating extraneous / exogenous DNA traceable and *attributable to an event* (for example, carryover of DNA during extraction stage) and/or *attributable to an individual (DNA source) in the laboratory* will be investigated, documented and submitted to the laboratory Quality Assurance manager for evaluation and advise on taking appropriate action(s).

The DNA analyst responsible for the above event will complete an anomaly log after the root cause analysis and supporting documentation has been reviewed and approved by the DNA technical manager who in turn will notify the QA Manager as stated above.

Contaminating extraneous / exogenous DNA that cannot be traced or attributed to a laboratory related cause (for example, disposable “sterile” lab consumables contaminated by a source(s) at the manufacturing or packaging facility) will be filed as an anomaly report after the root cause analysis and supporting documentation has been reviewed and approved by the DNA technical manager.

(Chapter 14: Corrective Actions)

Chapter 10: Equipment Calibration and Maintenance

The laboratory uses equipment that is suitable for the methods employed.

The laboratory has and follows a documented program for conducting performance checks and calibrating equipment and instruments.

A list of instruments along with their location and maintenance documents is maintained and updated by the DNA technician.

The following critical instruments are performance checked at least once every calendar year (annual) as well as when an interim check is deemed necessary:

1. A thermometer that is traceable to national or international standard(s) and is used for conducting performance checks;
2. Thermal cycler temperature verification system;
3. Monitoring Thermal cyclers including quantitative PCR;
4. Electrophoresis detection systems;
5. Robotic systems;
6. Genetic analyzers;
7. Mechanical pipettes

(Please refer to Instrument manuals, Vendor support information sources, Forensic Biology procedures and/or work instructions manuals for additional information).

If and when NDIS approved expert systems is used for database sample data analysis, it will deemed a critical instrument and the software will be recertified on a quarterly basis.

The laboratory has a schedule and follows a documented program to ensure that instruments and equipment are maintained properly.

The DNA technician ensures that Maintenance/Performance Check schedules/QC plans as well as documentation that these plans are implemented as stated are maintained in log books or binders. These log books are located near the relevant instruments and in the laboratory area where these instruments are used.

The laboratory performance checks new critical instruments and equipment and/or critical instruments and equipment that have undergone repair, service or calibration, before use in database and forensic casework analysis.

At a minimum, the following critical instruments or equipment are performance checked following repair, service and/or calibration:

Genetic analyzers

Robotic systems;

and,

Thermal cyclers including those used for quantitative PCR.

In the event an instrument fails unexpectedly or an incubator or refrigerator/freezer does not maintain the acceptable temperature range, the technical manager will be notified immediately and an appropriate course of action taken immediately.

Chapter 11: Documentation / Reports

The laboratory has and follows established documented procedures (Laboratory Quality Assurance manual) for taking and maintaining case notes to support the conclusions drawn in the laboratory reports.

The laboratory maintains all analytical documentation generated by analysts related to case analyses.

The laboratory retains in hard copy or electronic files, as appropriate, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could interpret and evaluate the data.

Once casework analysis and technical review of the data and pending case report is completed, and any outstanding technical issue(s), if applicable, have been resolved, the related GeneMapperID X project files created may be deleted.

All raw data files generated in the course of casework analysis shall be retained and archived as appropriate. Only these raw data files along with the appropriate procedures and work instructions manuals (maintained on the laboratory network) will be made available pursuant to discovery requests when filed with a court order.

The laboratory reports include at the very minimum the following information:

Case identifier(s),

Description of evidence examined,

Description of technology,

Locus or amplification system,

Results/conclusions/opinions,

Qualitative and/or quantitative interpretative statement,

Date issued,

Disposition of evidence,

Signature and title of the person(s) accepting responsibility for the content of the report. The signature on the report routinely belongs to the primary analyst who conducted the analysis and generated the report.

The DNA case report also contains the name of the analyst who conducted technical peer review.

The case report and the pages that contain the table(s) for STR typing results are treated as administrative documents/records.

The bench notes (except for the pages containing the STR typing results table(s) are treated as technical documents/records.

The laboratory has established and follows documented procedures (please refer to the laboratory Quality Assurance manual) to ensure the confidentiality of the database, casework known (reference) samples and, the information in DNA databases and DNA records, except as otherwise provided by applicable state and federal law.

The laboratory has and follows established documented procedures for the release of personally identifiable information relating to DNA records in accordance with applicable state or federal law.

The laboratory has and follows established documented procedures for the release of personally identifiable information in connection with a database hit.

(Please refer to the CODIS manual for details pertaining to database sample related documentation and reports).

Chapter 12: Review

The laboratory has and follows established documented procedures for reviewing DNA records and DNA database information, including the verification and resolution of database matches (CODIS manual).

The laboratory conducts and documents technical and administrative review of all DNA case files and reports/records to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

All technical reviews are conducted by individuals who are, or have been, qualified analysts in the methodology being reviewed.

The laboratory documents the completion of the technical review prior to uploading or searching in CODIS (please refer to the CODIS manual).

The laboratory documents the completion of technical review of forensic casework. This includes:

(a) Review of all case notes, worksheets, and electronic and/or printed electropherograms that support the conclusions,

(b) Review of all DNA typing data to verify that they are supported by raw or analyzed data (electronic and/or printed),

(c) Review of all genetic profiles to verify correct inclusions and exclusions, as applicable, as well as a review of any inconclusive result for compliance with laboratory guidelines,

(d) Review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained,

(e) Review of statistical analyses, as applicable,

(f) Review of the final report to verify that the results/conclusions/opinions are supported by the data and address each tested item and/or its *probative fraction*,

(g) Verification of eligibility all profiles prior to upload and search in CODIS as to whether they have the correct DNA types and correct specimen category. Eligibility of the profile for CODIS, verification of criteria for correct DNA types and appropriate specimen category of the genetic profile is also done by concordant assessments by a qualified analyst, technical reviewer, and/or technical manager.

Probative fraction (example): In a vaginal swab from a sex-assault case, the data generated from analyzing the male fraction, i.e. the sperm from the suspect in the sample.

The laboratory documents the elements of technical and administrative review in accordance with the forensic biology procedures and/or work instructions manuals.

The laboratory has and follows a documented procedure (discussion with / approval of DNA technical manager) to address unresolved discrepancies (e.g., data interpretation) in conclusions drawn between analysts and reviewers.

The laboratory has a system in place to ensure that the correct CODIS specimen categories have been assigned.

Administrative review of forensic casework (aspects of which may overlap and complement technical review) includes a review of the case file and final report for clerical errors and for the presence and accuracy of the information discussed in Chapter 11.

The laboratory documents the completion of the administrative review in accordance with the procedures and/or work instructions.

The laboratory has and follows a program that documents the annual monitoring of court (expert witness) testimony of laboratory personnel in accordance with the laboratory quality assurance manual.

Documentation of expert witness testimony evaluations are maintained by the laboratory Quality Assurance manager.

Chapter 13: Proficiency Testing

Analysts, technical (peer) reviewers and other personnel designated by the technical manager undergo semi-annual external proficiency testing (two tests each year) in each technology performed to the extent in which they participate in database and/or forensic casework sample/evidence analysis.

The laboratory quality assurance manager maintains proficiency test information and records.

Database sample analysts and forensic casework analysts using manual and/or automated methods will be proficiency tested in each methodology as applicable at least once per year to the extent in which they participate in DNA analysis.

If an analyst is qualified in multiple amplification test kits or systems for a specific technology, the analyst must be proficiency tested on each amplification test kit or system over the course of the year.

However, the individual must be proficiency tested on all the CODIS core loci and/or core sequence ranges for each semi-annual proficiency test cycle.

Newly qualified analysts will enter the external proficiency testing program within six months (or earlier) of the date of their qualification.

The laboratory has defined, documented, and consistently used the date that the proficiency test is due to the proficiency test provider (please refer to the laboratory Quality Assurance manual).

Each analyst is assigned and is expected to complete his/her own external proficiency test.

Team approach to proficiency testing is limited and is applicable only for biological screening of test items prior to DNA analysis.

The team approach is employed for this aspect (biological screening) of proficiency testing in order to mimic the manner in which real/actual items of evidence are handled by the laboratory.

This process ensures that workflow pattern(s) between the biological screening and DNA are kept consistent and similar between proficiency test sample(s) and casework/evidence sample(s) screening and processing (please refer to the Forensic Biology procedures and work instructions manuals for additional information on this topic).

The typing of all CODIS core loci are attempted for each technology performed as applicable.

The laboratory maintains the following records for proficiency tests:

Test set identifier;

Analyst(s) identity as applicable;

Date of analysis and completion/submission of results;

Copies of all data and notes supporting the conclusions;

Proficiency test results;

Discrepancies, if any, noted;

and,

Corrective actions, if any, taken.

The laboratory includes, at a minimum, the following criteria for evaluating proficiency test results:

All reported inclusions and exclusions are correct,

All reported genotypes / phenotypes correct or incorrect according to consensus results and/or consistent with the laboratory's interpretation guidelines,

Results reported as inconclusive / not interpretable are consistent with written laboratory guidelines

Inconclusive results, in accordance with standard operating procedures have been reviewed by the technical manager for compliance with laboratory guidelines, and

Discrepancies / errors, if any, as well as subsequent corrective actions have been documented,

Final reports have been graded as satisfactory or unsatisfactory

Documentation to show that no analytical errors were observed for the DNA profile typing data in reports graded as satisfactory, and,

Documentation showing that corrective actions were applied to administrative errors, if any.

The proficiency test participants will be informed of their final test results and this notification will be documented.

The technical manager will be informed of the results of all proficiency test participants and this notification will be documented.

The technical manager will inform the CODIS administrator of all technical/analytical (non-administrative) discrepancies that affect the typing results and/or conclusions at the time of discovery.

The technical manager will be responsible for determining whether an error in interpretation or typing shall be classified as an analytical error or not. This decision will be based on review of the analytical data to ensure compliance / consistency with the laboratory interpretation guidelines.

The laboratory will continue to use an external proficiency test provider(s) that complies/comply with the current proficiency testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/laboratory Accreditation Board (or current International Organization for Standardization, as applicable).

Chapter 14: Corrective Action

The laboratory Quality Assurance manual establishes a corrective action plan that is followed to address discrepancies detected in proficiency tests, database and forensic casework analysis.

The corrective action plan addresses, at a minimum, the following:

Defining what level/type of discrepancies are applicable to this practice

Identifying, when possible, the cause of the discrepancy

Effect of the discrepancy

Corrective actions taken

Preventive measures taken, where applicable, to minimize its occurrence

Documentation of all corrective actions maintained in accordance with the laboratory document retention policies and procedures.

Prior to implementation, all corrective actions will have the documented review and approval of the DNA technical manager. The laboratory Quality Assurance manager will be notified of events that would potentially invoke corrective actions.

Chapter 9: Information regarding anomaly reports.

Chapter 15: Audits

The laboratory undergoes annual audits in accordance with the FBI DNA Quality Assurance Standards and maintains documentation for this inspection.

The documentation will include proof that an external audit has been conducted at least once every two years by a qualified auditor who is a current or previously qualified analyst in the laboratory's current DNA technologies and platform.

At least one member of the audit team will be a current or previously qualified analyst from a databasing laboratory.

The laboratory maintains audit documentation of those individuals (i.e. CODIS administrator – casework and database, technical manager and analysts) that have had their education, experience and training qualifications evaluated and approved during two external audits.

The laboratory maintains documentation for those validations previously evaluated and approved during one external audit.

For internal / annual audits, the laboratory maintains documentation that the auditors for this inspection included a qualified auditor who is a current or previously qualified analyst in the laboratory's current DNA technologies and platform.

Internal and external audits are performed pursuant to FBI QA Standard 15.1 and conducted using the FBI Quality Assurance Standards Audit Document in effect at the time of the audit.

Internal and external audit documents, and corrective actions, if any, are submitted for review to the technical manager to ensure that findings, if any, are appropriately addressed.

The laboratory, which is an NDIS participating laboratory, will provide all external audit documentation and laboratory responses to the FBI within 30 days of the laboratory's receipt of the audit documents/report.

Previous DNA internal/annual and external audit documents are retained by the technical manager and available for auditor inspection.

Chapter 16: Safety

The DNA laboratory does not maintain a section specific safety manual.

Please refer to the laboratory Safety manual for information regarding annual review of the environmental health and safety program that includes, at a minimum, a blood-borne pathogen and chemical hygiene plan and training.

Chapter 17: Outsourcing

If samples are outsourced to vendor laboratories for processing, the vendor laboratory selected shall be one that complies with the FBI Quality Assurance Standards for DNA databasing and forensic DNA testing /casework laboratories and the accreditation requirements of federal law. Documentation of such compliance will be maintained by our laboratory.

When this NDIS participating laboratory is the outsourcing entity, the DNA technical manager will document and maintain the approval of the technical specifications of the outsourcing agreement before it is awarded.

If the vendor laboratory is performing DNA analysis for a law enforcement agency or entity other than the NDIS laboratory, the vendor laboratory shall obtain documented approval from the technical manager of this NDIS participating laboratory accepting ownership of the DNA data generated prior to initiating analysis.

Our laboratory will ensure that the vendor laboratory uses the same technology platform and typing amplification kit for its DNA data analysis as our laboratory.

Prior to uploading or accepting data for upload and search in CODIS, the DNA technical manager of our laboratory will document the prior approval of the technical specifications of the outsourcing agreement and/or documents the approval of acceptance of ownership of the DNA data.

When our laboratory is the primary outsourcing entity, it follows and documents the established and appropriate quality assurance procedures to verify the integrity of the data received from the vendor laboratory including, but not limited to, random reanalysis of samples (database/forensic casework).

When the primary outsourcing entity is a law-enforcement or other non-NDIS participating agency, the data is received (by our lab) through the outsourcing agency.

Prior to acceptance of the data, information pertaining to the nature of the evidence submitted is collected from the case officers and investigators.

Eligibility of the sample DNA profiles for entry and search in CODIS is determined by communication with the submitting officers.

Inclusion of Quality Control samples is required to conduct a technical review of outsourced data.

If our laboratory is the primary outsourcing entity, an on-site visit plan of the vendor laboratory will be conducted in compliance with the FBI Quality Assurance Standards.

This plan will include documentation of the on-site visit prior to initiation of analysis.

The on-site visit will be conducted by the DNA technical manager or a qualified analyst designated by the technical manager.

The qualifications of the designee will include current or previous qualification in the technology, platform and typing amplification test kit used to generate the DNA data.

If the primary outsourcing entity is not our laboratory, then, documentation of results pertaining to a site visit conducted by qualified individuals from another NDIS participating laboratory will be obtained and retained for quality assurance purposes and audit requirements.

Our laboratory will ensure that the individuals conducting the "proxy site visit" shall be trained and qualified in the same technology, platform and typing amplification kit being used by our laboratory.

For new contracts (contracts beginning after 1 July 2009), the DNA technical manager or a designated qualified laboratory DNA analyst will conduct and document the site visit prior to the date sample processing begins.

The person conducting the site-visit will be currently or previously qualified in the technology, platform, and typing amplification test kit used to generate the DNA data.

If the outsourcing agreement (our laboratory or other non-NDIS participating agency) extends beyond one year, an annual site visit will be conducted by the technical manager or by proxy and their results reviewed and documented by the technical manager to acknowledge acceptance of the on-site visit results.

The elements captured by the on-site visit will include, at a minimum:

Facilities where the samples are processed,

Review of the quality assurance / quality control procedures,

Review of the standard operating procedures,

Corrective action reports, if applicable,

and,

Interpretation guidelines and report writing conventions employed.

Our laboratory has procedures for performing an on-site visit of the vendor laboratory. For all new contracts (those beginning after 1 July 2009), the site visit will be conducted prior to the initiation of analysis.

Our laboratory has and follows established and documented procedures (forensic biology procedures and/or work instructions manuals and outsourced data review checklist) to verify and the integrity of the data received from a vendor laboratory by performing a technical review.

The technical review is performed prior to upload to and search in the DNA database and includes, at a minimum,

1. A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms / images),
2. A review of associated controls,
3. Internal lane standards and allelic ladders to verify that expected results were obtained, and,
4. Verification of DNA types, eligibility and the correct specimen category for entry into CODIS.

A review of the final report, if provided, is used to verify that the results and conclusions are supported by the data and that each tested item and/or its probative fraction submitted to the vendor is addressed.

Technical review of the vendor laboratory data is generally conducted by the DNA technical manager of our laboratory who may authorize and designate a qualified analyst to perform the data review prior to CODIS upload.

Appendix I

2012 R0 Page	2011 R1 Page	Location	Revision made
2	2	Introduction	Removed "(abbreviated as AK SCDL)"
2	2	Introduction	Changed "(2009)" to "(2010 Census)"
2	2	Introduction	Inserted "The laboratory"
2	2	Introduction	Changed "STR's" to "STR (Short Tandem Repeats)"
2	2	Introduction	Changed "(platform AB3130xl - PP16 - 32 cycles amplification)" to "none"
3	3	Goals and Objectives	Changed "AK SCDL Laboratory Quality Assurance Manual" to "The laboratory Quality Assurance manual for quality standards which are applicable to all disciplines of the crime laboratory"
3	3	Chapter 1	Changed "(1) Standard 1 - FBI Quality Assurance Standards (QAS) document for forensic DNA testing and DNA databasing laboratories, effective 01 September 2011." to "1. FBI Quality Assurance Standards (QAS) documents: Version(s) effective 01 September 2011 for Forensic DNA Testing laboratories and DNA Databasing laboratories."
3	3	Chapter 1	Changed from "AKSCDL DNA QA manual" to "The DNA QA manual"
3	3	Chapter 1	Removed "(2) AK SCDL Laboratory Quality Assurance Manual for quality standards that are applicable to all disciplines/sections of the crime laboratory"
3	3	Chapter 1	Changed "(3) AK SCDL Laboratory Safety Manual" to "2. The laboratory Safety Manual"
3	3	Chapter 1	Changed "(4) DNA Standard Operating Procedures manual" to "3. The Forensic Biology Procedures and Work Instructions manuals"
3	3	Chapter 1	Changed from "(5) DNA Section Training Manual" to "4. The DNA Training Manual"
3	3	Chapter 2	Changed "and Reference:" to " In addition, please refer to:"
5	4	Chapter 3	Changed "The laboratory maintains and follows procedures (please refer to the Laboratory Quality Assurance manual) regarding document retention which addresses policies regarding" to "Document Retention policies: Please refer to the laboratory Quality Assurance manual regarding procedures pertaining to document retention policies for the following:"
5	4	Chapter 3	Changed "Standard 15" to "FBI QA Standard 15"

2012 R0 Page	2011 R1 Page	Location	Revision made
5	4	Chapter 3	Changed "The review" to "The manual(s) review"
5	4	Chapter 3	Changed "A checklist maintained along with the quality manual contains the signatures of the analysts and the date the annual review was completed. This annual review includes the quality manual, training manual, and standard operating procedures manual (Please see Chapter 9: Analytical Procedures). A checklist for this annual review is maintained with each relevant manual in order to document the review and address procedures for updating the manual(s)." to "Checklists are maintained as hard copies for each of the manuals listed below until all required signatures/initials of the analysts along with the date their annual review of relevant documents was completed. The checklists are then converted to an electronic format (pdf file) and stored in LIMS. This annual review document list currently includes the DNA Quality Assurance manual, Forensic Biology manuals (procedures and work instructions), DNA Training Manual, Biological Screening Training Manual, and, CODIS Manual."
6	5	Chapter 4	Changed "Documentation that specifies the responsibility, authority, and interrelation of all personnel who manage, perform, and/or verify work affecting the validity of DNA analysis is maintained. The Laboratory Quality Assurance manual contains information pertaining to the laboratory organizational chart." to "The laboratory organizational chart contains documentation that specifies the responsibility, authority, and interrelation of all personnel who manage perform and/or verify work affecting the validity of DNA analysis."
6	5	Chapter 4	Inserted "Forensic Biology"
6	5	Chapter 4	Inserted "information contained"
6	5	Chapter 4	Removed "Please refer to the Laboratory QA Manual for overall AK SCDL organization and management"

2012 R0 Page	2011 R1 Page	Location	Revision made
10	8	Chapter 5	Removed "Every analyst has a minimum of a BA/BS (two analysts have a MS) degree in relevant subject areas."
12	10	Chapter 7	Inserted "used up/"
12	10	Chapter 7	Changed "use the extract" to "use/consume the entire extract"
13	11	Chapter 7	Changed "databasing section" to "databasing laboratory"
15	12	Chapter 8	Changed "including" to "will include at a minimum:"
16	12	Chapter 8	Removed "(reference: laboratory quality assurance manual and DNA standard operating procudes manual"
16	12	Chapter 8	Inserted "(Please refer to the laboratory Quality Assurance manual and Forensic Biology procedures and work instructions)"
17	13	Chapter 9	Changed "procedures" to "protocols"
17	13	Chapter 9	Inserted "(Forensic Biology procedures and work instructions)"
17	13	Chapter 9	Removed "as described in"
17	13	Chapter 9	Inserted "when applicable"
17	13	Chapter 9	Changed "standard operating procedures (SOP)" to "analytical protocols"
17	13	Chapter 9	Inserted "The laboratory does not permit interim updates to the manuals by hand or electronic means."
17	13	Chapter 9	Changed "SOP" to "protocols (Forensic Biology procedures/work instructions)"
17	13	Chapter 9	Changed "procedures (work instructions)" to "protocols (procedures / work instructions)"
18	13	Chapter 9	Inserted "– i.e., use on microscopy slides. Such items can be used until they no longer adequately satisfy the intended use- for example, the Permount becomes too viscous or the Xylene fails to reduce the viscosity of the Permount or renders the Permount too opaque to view the materials on the slide."

2012 R0 Page	2011 R1 Page	Location	Revision made
18	13	Chapter 9	Changed "(reference: DNA standard operating procedures manual for information and rationale for designating reagents as critical or non-critical)." to "(Forensic Biology procedures and/or work instructions manual(s) for information and rationale for designating reagents as critical or non-critical)."
18	14	Chapter 9	Changed "(reference: CODIS manual for detailed information)." to "(CODIS manual)"
19	14	Chapter 9	Changed "procedures" to "protocols"
19	14	Chapter 9	Inserted "/substantive"
19	14	Chapter 9	Inserted "or work instructions"
19	14	Chapter 9	Changed "(reference: DNA standard operating procedures manual)" to "(DNA procedures and/or work instructions manuals)"
19	15	Chapter 9	Changed "procedures (reference: DNA standard operating procedures manual)" to "protocols (DNA procedures and/or work instructions manuals)"
20	15	Chapter 9	Changed "(Reference: Chapter 14 for more information)" to "(Chapter 14: Corrective Actions)"
21	16	Chapter 10	Changed "(Reference: Instrumentation manuals; vendor support information sources; DNA standard operating procedures manual for additional information)" to "(Please refer to Instrument manuals, Vendor support information sources, Forensic Biology procedures and/or work instructions manuals for additional information)."
21	16	Chapter 10	Inserted "and when"
23	17	Chapter 11	Changed "(laboratory quality assurance manual)" to "(Laboratory Quality Assurance manual)"
24	18	Chapter 11	Changed "Please refer to the CODIS manual for details pertaining to database sample related documentation and reports." to "(Please refer to the CODIS manual for details pertaining to database sample related documentation and reports)."
25	18	Chapter 12	Changed "(reference: CODIS manual)" to "(CODIS manual)"
25	18	Chapter 12	Changed "(reference CODIS manual)" to "(please refer to CODIS manual)"
25	18	Chapter 12	Removed "(reference: laboratory standard operating procedures manual)"
25	19	Chapter 12	Removed "(reference: laboratory standard operating procedures manual)"

2012 R0 Page	2011 R1 Page	Location	Revision made
26	19	Chapter 12	Changed "standard operating procedures manual" to "forensic biology procedures and/or work instructions manuals."
26	19	Chapter 12	Inserted "(discussion with / approval of DNA technical manager)"
26	19	Chapter 12	Inserted "(e.g., data interpretation)"
26	19	Chapter 12	Changed "standard operating procedures" to "procedures and/or work instructions."
26	19	Chapter 12	Changed "Results" to "Documentation"
27	20	Chapter 13	Changed "(reference Laboratory Quality Assurance Manual)" to "(please refer to the laboratory Quality Assurance manual)"
27	20	Chapter 13	Changed "Please refer to the DNA SOP manual for procedures regarding proficiency test report writing format." to "(please refer to the Forensic Biology procedures and work instructions manuals for additional information on this topic)."
30	22	Chapter 14	Changed "Define" to "Defining"
30	22	Chapter 14	Changed "Identify" to "Identifying"
30	22	Chapter 14	Inserted "The laboratory Quality Assurance manager will be notified of events that would potentially invoke corrective actions."
30	22	Chapter 14	Inserted "Chapter 9: Information regarding anomaly reports."
32	24	Chapter 16	Changed "Please refer to the AK SCDL Laboratory Safety Manual for documentation of an environmental health and safety program that includes, at a minimum, a blood-borne pathogen and chemical hygiene plan as well as a documented training on the blood-borne pathogen and chemical hygiene plan. The laboratory's environmental health and safety plan is reviewed annually and this review is documented." to "Please refer to the laboratory Safety manual for information regarding annual review of the environmental health and safety program that includes, at a minimum, a blood-borne pathogen and chemical hygiene plan and training."
33	25	Chapter 17	Changed "the AK SCDL (NDIS participating laboratory)" to "this NDIS participating laboratory"
33	25	Chapter 17	Removed "(AK SCDL)"
33	25	Chapter 17	Changed "the AK SCDL" to "our laboratory"

2012 R0 Page	2011 R1 Page	Location	Revision made
33	25	Chapter 17	Inserted "(by our lab)"
34	26	Chapter 17	Changed "AK SCDL" to "DNA"
34	26	Chapter 17	Changed "the AK SCDL" to "our laboratory"
34	26	Chapter 17	Removed "This policy applies only to those contracts entered into by the participating agencies prior to July 1, 2009."
34	26	Chapter 17	Changed "For contracts that begin after this date," to "For new contracts (contracts beginning after 1 July 2009), "
35	26	Chapter 17	Changed "For contracts commencing after 1 July 2009" to "For all new contracts (those beginning after 1 July 2009)"
35	26	Chapter 17	Changed "(reference standard operating procedures manual and outsourced data review checklist)" to "(forensic biology procedures and/or work instructions manuals and outsourced data review checklist)"
35	27	Chapter 17	Inserted "DNA"
35	27	Chapter 17	Changed "AK SCDL" to "our laboratory"
35	27	Chapter 17	Inserted "prior to CODIS upload"